WOE of Anti-CD20 Therapies

Last Update: Mar 26, 2025
The Wearing-off Effect of Anti-CD20 Therapies in Patients With Multiple Sclerosis
ClinicalTrials.gov Identifier:
NCT06121349
Novartis Reference Number:COMB157AUS22
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The nature, intensity, and prevalence of this wearing-off effect remain poorly understood. To our knowledge, there is no consensus in the literature on what symptoms constitute a wearing-off effect, nor is there a single validated scale that measures wearing-off effect. The current study will explore the wearing-off effect associated with OCR and OMB, using a variety of validated scales assessing MS symptoms (i.e., fatigue, mobility, pain, depression, cognition), as well as some global questions on wearing-off. In addition, impact of worsening of MS symptoms on patients' health-related quality of life (HRQoL) and their work productivity will be assessed using relevant MS-specific validated scales This will be a non-interventional, primary data collection study in patients with MS treated with an established anti-CD20 treatment regimen (OCR or OMB) in the United States. Patients who satisfy the inclusion criteria and consent to participate in the study will be surveyed at four timepoints at the beginning and the end of OCR or OMB treatment cycles according to the following assessment schedule:

* Assessment 1. 0-10 days before 1st dose post-enrollment (index dose)
* Assessment 2: 5-14 days after index dose
* Assessment 3: 0-10 days before 2nd dose post-enrollment (follow-up dose)
* Assessment 4: 5-14 days after follow-up dose dose

Condition
Multiple Sclerosis
Overall Status
Recruiting
Number of Participants
150
Start Date
Dec 04, 2023
Completion Date
Dec 31, 2025
Gender
All
Age(s)
21 Years - 85 Years (Adult, Older Adult)

Interventions

Drug

ocrelizumab

infusion therapy administered every six months
Drug

ofatumumab

self-injectable every month

Eligibility Criteria

Inclusion Criteria:

OCR sample:

* Self-reported diagnosis of RMS, SPMS or CIS
* ≥21 years old at the time of initial contact
* Under treatment with OCR at the time of initial contact
* Have been on OCR for ≥ 1 year at the time of initial contact (i.e., prevalent users)
* Able to answer the questionnaires in English

OMB sample

* Self-reported diagnosis of RMS, SPMS or CIS
* ≥21 years old at the time of initial contact
* Under treatment with OMB at the time of initial contact
* Have been on OMB for ≥6 months at the time of initial contact (i.e., prevalent users)
* Able to answer the questionnaires in English

Exclusion Criteria:

OCR sample:

* Currently participating in a clinical trial involving MS drugs
* Last Ocrevus infusion was less than 3 months back

OMB sample:

Currently participating in a clinical trial involving MS drugs

United States

Novartis Investigational site

Recruiting

East Hanover,New Jersey,07936,United States

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06121349*

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